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TITLE: Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

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14. ABSTRACT The proposed project is a fully-powered randomized controlled trial of a smartphone-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking in the previous 4 months. After tailoring the content of the SP-BI intervention for NG soldiers, the proposed study will screen ~ 3,100 individuals over the three year enrollment period as part of the larger ongoing longitudinal assessment of ONG members in the OHARNM MHI, to identify 750 participants with at-risk drinking. These ONG members will be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed for one year.					
15. SUBJECT TERMS Ohio National Guard, Mental Health, Alcohol Use Disorders, Risky alcohol use, SBIRT (Screening, Brief Intervention, Referral to Treatment) model, Risky					
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- 1. INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This project is a fully-powered randomized controlled trial of a smartphone-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 3 months. After tailoring the content of the SP- BI for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the Ohio Army National Guard Mental Health Initiative (OHARNG MHI), to identify 750 participants with unhealthy drinking. These Guard members will then be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

The specific aims are to compare SP-BI and EUC in:

1. Reducing the frequency and intensity of at-risk drinking at 4 -, 8- and 12-months;
2. Decreasing binge drinking at 4 -, 8- and 12 months.

The secondary aims are to:

1. Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 4 -, 8- and 12-months;
2. Examine if deployment status moderates the effect of intervention assignment (SP-BI or EUC) on post-intervention drinking, depressed feelings, and other substance use.

- 2. KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Alcohol screening, brief intervention, drinking, military, eHealth, mHealth, social support

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population

Subtask 1

Facilitate focus groups, consisting of Ohio NG leadership and soldiers to develop, refine, and tailor the screening questionnaires, assessments, and risk management procedures.

Subtask 2

Create mobile phone app – and text-based alcohol brief intervention program and a project management tracking system in the first 9 months of Year 1.

Task #2: Data Collection

Subtask 1

Hire (as necessary) and train all study personnel in Year 1, with ongoing trainings held each year as needed.

Subtask 2

Starting in the 4th quarter of Year 1 through Year 4, enrollment of up to 750 participants (~250 participants/year over 3 years) utilizing the Ohio Army National Guard Mental Health Initiative platform for recruitment

Subtask 3

Participant follow-up at 4, 8, and 12 months through Year 5 (N=750)

Task #3: Data Dissemination

Subtask 1

Starting in Year 2, performance of descriptive analysis of the data including, but not limited to hazardous alcohol use and deployments, and hazardous alcohol use with co-morbid illnesses, i.e. PTSD, depression.

Subtask 2

Upon completion of data collection, at least 1 submission to a peer-reviewed journal will be derived from the study data

Subtask 3

Starting in Year 2, presentations each year of the most recent alcohol data, i.e. at advisory board meetings, poster/symposium presentations at scientific conferences, and presentations for the Ohio NG, as requested.

Task #4: Oversight Meetings

Subtask 1

External Scientific Advisory Board, providing critical feedback on the scientific merit of the project, will be held once annually, Years 1-5.

Subtask 2

Administrative Advisory Board, providing guidance on non-scientific issues, will be held once annually, Years 1-5.

Subtask 3

Sponsor Scientific Meeting (as requested) consisting of programmatic and scientific leaders to provide a scientific and fiscal update.

Subtask 4

Data Safety Monitoring Board, provide information as needed to the quarterly DSMB meetings, held by the Coordinating Center

Task #5: Regulatory & Reporting

Subtask 1

Initial Submission in Year 1, Continuing Reviews in Years 2-5, and addendum submissions as needed, to applicable local IRBs of record

Subtask 2

Obtain Certificate of Confidentiality from DHHS in Year 1

Subtask 3

Initial Submission in Year 1, Continuing Review in Years 2-5, and applicable submissions to the DoD Office of Research Protections

Subtask 4

Quarterly financial reporting to USAMRAA, as required, in Years 1-5

Subtask 5

Annual progress report to USAMRMC in Years 1-4, with a Final Report at the end of Year 5.

Subtask 6

Progress reports to sponsoring agency (as requested)

What was accomplished under these goals?

Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population – 95%

The following progress has been made with app development:

- Weekly development meetings continued to occur with the University of Michigan Center for Health, Communications, and Research (CHCR), the group programming the phone app.
- CHCR incorporated feedback from testing in to the app, repaired bugs in the app software, finalized the app and submitted final updates to app stores where it has been available for study participants to download.
- CHCR updated the app to remove all references to contingency management.
- CHCR made data dictionaries available to coordinating center staff which will assist in running reports on app data once the study starts
- CHCR continued to make adjustments and updates to the app as needed when issues have been noted by subjects and study staff.

Study staff compiled videos and news articles to include in the newsfeed section of the app. Staff have finished writing manuals to assist research coordinators in using various app features including the dashboard, the newsfeed and the health coach. Health coach identities have been developed and posts to encourage in-app discussion have been created.

Task #2: Data Collection – 15% completed

The University of Toledo hired their research coordinator for the project in October 2016. Since then the study team worked to complete training on all assessments and ensuring that study coordinators at both UT and UHCMC are familiar with the content of the app and dashboard. Study coordinators also practiced the pre-screening and verbal consenting process for the study as well as administering the Timeline Followback assessment.

Study manuals to assist research coordinators in using REDCap were completed and finalized. The manual covers how to navigate the project database, successfully complete data entry, and the role of the data coordinator in ensuring data quality. It also provides guidelines and instructions on contacting participants, survey procedures and how to handle subjects who flag for suicidal ideation either on the phone or in their survey.

The data coordinator programmed all assessments in to the REDCap database for this study. Study staff at all sites tested the database and all of its functionality. Modifications to the workflow were made based on that feedback and the database was finalized and moved to

production mode so data collection could begin. In addition, the data coordinator trained study coordinators on how to use REDCap and has provided ongoing assistance as needed.

The study was approved by site IRBs and HRPO for all 3 sites.

Work flow was established between the coordinating site and Abt Associates, Inc. (the survey firm completing the telephone surveys for the main platform project) to apply our pre-screening criteria so we may contact potentially eligible subjects based on that criteria.

Enrollment for this study began on March 7, 2017 once all the necessary approvals were secured. As of August 31, 2017, Abt. Associates Inc. has referred 1,034 participants, 151 of which were eligible to pre-screen for the study. From this group, 45 participants consented and continued with the screening procedures. We have randomized 28 subjects; 15 to the Smartphone App group and 13 to the control group. More detailed enrollment information can be found in the flow chart included in this report.

	Enrolled (Randomized)
Case Western Reserve University	10
University of Toledo	18
Total	28

Due to the large proportion of participants (approximately 53%) in the platform project who are no longer active in the Ohio Army National Guard (OHARNG), it was determined that in addition to recruitment from the platform project, we will need to recruit outside of the platform project in order to meet our recruitment goal of 750 randomized subjects. The study PIs had a conference call with CPT David Kirker, Director of Psychological Health, Behavioral Health Science Officer, Ohio Army National Guard, on August 4, 2016 to discuss possible options for recruitment. CPT Kirker suggested inviting study staff to participate in drill weekends when Personal Health Assessments are completed. He suggested we have a table set up to talk to, answer questions and enroll interested OHARNG soldiers. CPT Kirker indicated that he would take this request to the appropriate people in the ONG and help move forward the necessary approvals. We have revised the scope of work to reflect this potential change and will be submitting this to the Science Officer for review.

Task #3: Data Dissemination – 0% completed

There were no activities related to this task completed over the reporting period.

Task #4: Oversight Meetings – 50% completed

Ms. Lynn Massey, Project Coordinator at UM, attended the 2016 Joint Substance Abuse IPR, which was held September 20-21, 2016, and presented on the project. The following was presented:

1. Background and Rationale

o Problem Addressed

- Hazardous use of alcohol is a significant problem in the National Guard members that contributes to and complicates other problems including PTSD, depression,

- suicidality, lowered resilience and work performance.
 - Studies consistently find that substantial number of Guard members misuse alcohol.
 - Addressing misuse is particularly challenging in reserve component Soldiers who are geographically dispersed and must divide their time between military and civilian responsibilities.
 - Theoretical Rationale
 - Screening, Brief Intervention and Referral to Treatment (SBIRT) model has been shown to effectively impact misuse on population basis.
 - An eHealth intervention, tailored to National Guard, could provide a cost effective tool to enhance alcohol programming.
- 2. Uniqueness/Military Relevance
 - Phase I of the study developed a mobile phone app for delivering SBIRT specifically tailored to the unique needs and characteristics of the National Guard:
 - Smartphone apps have many advantages over other approaches:
 - Allows for/encourages frequent short interactions
 - Are an extension of the person (his/her social milieu) – it is always there with you
 - May overcome shortcomings of previous studies for engaging and retaining military members in the intervention
 - The app incorporates, in a unique blend, tactics that hold promise such as: tracking of individually set behavioral goals, contingency management, engagement approaches, peer counseling through a remote coach, ongoing tailored educational notices
 - Close collaboration with Guard staff ensures relevance of intervention
 - Phase II is a systematic randomized controlled study of the app intervention compared to control condition
- 3. Research Questions and Hypotheses
 - Aim 1: Compare the SP-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 3, 6, and 12 months post-intervention;
 - Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.
 - Aim 2: Compare the SP-BI and EUC conditions for binge drinking at 3-, 6- and 12 months.
 - Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.
 - Secondary AIM 1: Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12 months.
 - Hypothesis: Participants randomized to the SP-BI condition will significantly reduce the frequency of illicit drug use compared to participants in the EUC condition.
 - Secondary AIM 2: Examine the impact of the interaction of deployment status with intervention condition (SP-BI or EUC) on 3-, 6- and 12-month measures of alcohol and drug use.
 - Hypothesis: NG members who have been deployed in OEF/OIF/OND are expected to have higher risk of at-risk drinking compared to those who have not been deployed. We hypothesize that individuals who have been deployed will be less likely to change their drinking than those who have not been deployed. However, the smart phone app will address individual concerns and issues related to deployment.

4. Design and Methodology
 - Phase I: Development of Phone App Intervention
 - Informed by literature and initial experience in NIAAA-funded Michigan National Guard Web-based study
 - Investigators and app developers, in collaboration with a team of Ohio Guard members, brainstormed best options for phone app
 - Focused on shortening initial interaction (compared to web approaches) and maximizing engagement in an ongoing therapeutic/educational interaction
 - Emphasized relevance to complex life patterns of Guard members (e.g. military commitment, civilian employment, other civilian roles, deployment disruptions and stress)
 - Phase II: Randomized Trial of App Intervention
 - Participants are selected from OHARNG platform study, screened for eligibility, then consented
 - Eligibility:
 - Past 3-month AUDIT-C score of 5 for men and 4 for women
 - Currently serving in the OHARNG
 - Not in substance use treatment
 - Own a smartphone
 - Complete baseline assessment (~40 minutes)
 - Randomization stratified by gender and severity of use
 - Two groups:
 - Smart Phone App Brief Intervention (SP-BI) (12 weeks)
 - Enhanced Usual Care (EUC) (Brochure with Resources)
 - 3, 6, 12 month follow-up assessments
 - Payment: \$35 each/four assessments; SP-BI can earn up to \$100 for using the features in the app during 12-week intervention
5. Anticipated Flowchart
6. Measures Repeated at all Time Points
7. Study Progress
 - IRB:
 - Case –IRB approval obtained; submitted documents to HRPO waiting on approval
 - UMichigan – IRB approved and documents submitted to HRPO; waiting on approval
 - UToledo – submitted to IRB, recently sent back requested changes from IRB; HRPO submission pending
 - Certificate of Confidentiality obtained from NIH
 - Project Development:
 - Twice monthly meetings to work on IRB materials, Certificate of Confidentiality, ClinicalTrials.gov, and coordination with all IRB's
 - Monthly meetings between Case Western, Michigan and Toledo to develop protocols, surveys, app intervention, manuals, etc.
 - Weekly meetings with app developers to design app, provide feedback, test and tweak
 - Regular meetings with Ohio Guard Advisory Board-providing insight and feedback during the app development stage
 - Recruitment:
 - Anticipate start of recruitment once HRPO approval is received in October

8. Results and Conclusions
 - Phase I: Development of Intervention App
 - App has been fully developed for both iOS and Android platforms, and is available in app stores
 - Beta testing for bugs ongoing
 - Demonstration of App (video)
 - Phase II:
 - Enrollment to commence October, 2016
9. Follow On Work
 - eHealth app interventions have many advantages, including the ability to present detailed interactive interventions and allow the Guard member to establish personalized plans for change and receive frequent reminders, updated information and virtual support services.
 - Based on results of these two studies (this phone app intervention and the NIAAA Web-based intervention) additional innovations will be proposed and tested in National Guard and other Reserve components.
 - Results from this study will inform future studies that attempt to further refine and increase the impact of population eHealth interventions on key substance use and other mental health problems in reserve component members.

The 2016 External Scientific Advisory Board (SAB) meeting took place on November 7, 2016. Attendees included:

- **Lori Davis, M.D.** - Chief of the Research and Development Service, Tuscaloosa VA Medical Center
- **Norah C. Feeny, Ph.D.** - Professor, Department of Psychological Sciences, Case Western Reserve University
- **Robert K. Gifford, Ph.D.** - Senior Project Director, Study to Assess Risk & Resilience Among Service Members (STARRS); Executive Officer, Center for the Study of Traumatic Stress, Department of Psychiatry, USUHS
- **Robert Hammond, Psy.D.** - Chief Behavioral Health Officer, Ohio National Guard; Psychologist, Louis Stokes VA Medical Center
- **Terence M. Keane, Ph.D.** - Associate Chief of Staff for Residency & Development, VA Boston Healthcare System; Assistant Dean for Research, Professor & Vice Chairman, Division of Psychology, Boston University
- **Richard A. McCormick, Ph.D.** - Senior Scholar, Center for Healthcare Research & Policy, MetroHealth Medical Center, Case Western Reserve University
- **Thomas A. Mellman, M.D.** - Prof Psychiatry, Director, Clinical and Translational Research and Stress and Sleep Studies, Howard University College of Medicine

The following was presented at this meeting:

1. Background and Rationale
 - Problem Addressed
 - Hazardous use of alcohol is a significant problem in the National Guard members that contributes to and complicates other problems including PTSD, depression, suicidality, lowered resilience and work performance.
 - Studies consistently find that substantial number of Guard members misuse alcohol.

- Addressing misuse is particularly challenging in reserve component Soldiers who are geographically dispersed and must divide their time between military and civilian responsibilities.
 - Theoretical Rationale
 - Screening, Brief Intervention and Referral to Treatment (SBIRT) model has been shown to effectively impact misuse on population basis.
 - An eHealth intervention, tailored to National Guard, could provide a cost effective tool to enhance alcohol programming.
- 2. Uniqueness/Military Relevance
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 - The app incorporates, in a unique blend, tactics that hold promise such as: tracking of individually set behavioral goals, contingency management, engagement approaches, peer counseling through a remote coach, ongoing tailored educational notices
 - Close collaboration with Guard staff ensures relevance of intervention
 - Phase II is a systematic randomized controlled study of the app intervention compared to control condition
- 3. Research Questions and Hypotheses
 - The specific aims are to compare SP-BI and EUC in:
 - Reducing the frequency and intensity of at-risk drinking at 3 -, 6- and 12-months;
 - Decreasing binge drinking at 3-, 6- and 12 months.
 - Hypotheses for specific aims:
 - Compare the SP-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 3, 6, and 12 months post-intervention;
 - Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.
 - Compare the SP-BI and EUC conditions for binge drinking at 3-, 6- and 12 months.
 - Hypothesis: Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.
- 4. Design and Methodology
 - Phase I: Development of Phone App Intervention
 - Informed by literature and initial experience in NIAAA-funded Michigan National Guard Web-based study
 - Investigators and app developers, in collaboration with a team of Ohio Guard members, brainstormed best options for phone app
 - Focused on shortening initial interaction (compared to web approaches) and maximizing engagement in an ongoing therapeutic/educational interaction
 - Emphasized relevance to complex life patterns of Guard members (e.g. military commitment, civilian employment, other civilian roles, deployment disruptions and

- stress)
- Phase II: Randomized Trial of App Intervention
 - Participants are selected from OHARNG platform study, screened for eligibility, then consented
 - Eligibility:
 - Past 3-month AUDIT-C score of 5 for men and 4 for women
 - Currently serving in the OHARNG
 - Not in substance use treatment
 - Own a smartphone
 - Complete baseline assessment (~40 minutes)
 - Randomization stratified by gender and severity of use
 - Two groups:
 - Smart Phone App Brief Intervention (SP-BI) (12 weeks)
 - Enhanced Usual Care (EUC) (Brochure with Resources)
 - 3, 6, 12 month follow-up assessments
 - Payment: \$35 each/four assessments; SP-BI can earn up to \$100 for using the features in the app during 12-week intervention
- 5. Study Progress
 - IRB
 - Case –IRB approval obtained; submitted documents to HRPO waiting on approval
 - UMichigan – IRB approved and documents submitted to HRPO; waiting on approval
 - UToledo – submitted to IRB, recently sent back requested changes from IRB; waiting on HRPO approval
 - Certificate of Confidentiality obtained from NIH
 - Project Development:
 - Twice monthly meetings to work on IRB materials, Certificate of Confidentiality, ClinicalTrials.gov, and coordination with all IRB's
 - Monthly meetings between Case, Michigan and Toledo to develop protocols, surveys, app intervention, manuals, etc.
 - Weekly meetings with app developers to design app, provide feedback, test and tweak
 - Regular meetings with Ohio Guard Advisory Board-providing insight and feedback during the app development stage
 - Recruitment:
 - Anticipate start of recruitment once HRPO approval is received
- 6. Deliverables
 - Product to be Delivered
 - Fully programmed app-based alcohol brief intervention, tailored for National Guard members, produced with input from the Guard
 - Support materials (training materials, manuals) to support the management of the app by a Guard mental health or resilience technician, with input on content by Guard professional mental health/resilience staff
 - App program developed to allow it to be easily adapted to other military populations. Ohio is a good venue for such development- demographics mirror national demographics in most ways.
- 7. Follow On Work
 - eHealth app interventions have many advantages, including the ability to present detailed

- interactive interventions and allow the Guard member to establish personalized plans for change and receive frequent reminders, updated information and virtual support services.
- Based on results of these two studies (this phone app intervention and the NIAAA Web-based intervention) additional innovations will be proposed and tested in National Guard and other Reserve components.
- Results from this study will inform future studies that attempt to further refine and increase the impact of population eHealth interventions on key substance use and other mental health problems in reserve component members.

The Administrative Advisory Board meeting was held on March 9, 2017 at Rickenbacker Air National Guard Base in Columbus Ohio with members of the ONG leadership in attendance, including Assistant Adjutant General for Army, Major General John C. Harris, Jr. Dr. Blow presented the information outlined below and the Guard leadership had the opportunity to ask and have answered questions about the study.

Background and Rationale

Problem Addressed

- Hazardous use of alcohol is a significant problem in the National Guard members that contributes to and complicates other problems including PTSD, depression, suicidality, lowered resilience and work performance.
- Studies consistently find that substantial number of Guard members misuse alcohol.
- Addressing misuse is particularly challenging in reserve component soldiers who are geographically dispersed and must divide their time between military and civilian responsibilities.

Theoretical Rational

- Screening, Brief Intervention and Referral to Treatment (SBIRT) model has been shown to effectively impact misuse on population basis.
- An eHealth intervention, tailored to National Guard, could provide a cost effective tool to enhance alcohol programming.

Research Questions and Hypotheses

The specific aims are to compare SP-BI and EUC include:

- Reducing the frequency and intensity of at-risk drinking at 4 -, 8- and 12-months;
- Decreasing binge drinking at 4-, 8- and 12 months.

Hypotheses for specific aims:

- Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.
- Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.

Design and Methodology

Phase I: Development of Phone App Intervention

- Informed by literature and initial experience in NIAAA-funded Michigan National Guard Web-based study
- Investigators and app developers, in collaboration with a team of Ohio Guard members, brainstormed best options for phone app

- Focused on shortening initial interaction (compared to web approaches) and maximizing engagement in an ongoing therapeutic/educational interaction
- Emphasized relevance to complex life patterns of Guard members (e.g. military commitment, civilian employment, other civilian roles, deployment disruptions and stress)

Phase II: Randomized Trial of App Intervention

- Participants are selected from OHARNG platform study, screened for eligibility, then consented
- Eligibility:
 - Past 4-month AUDIT-C score of 5 for men and 4 for women
 - Currently serving in the OHARNG
 - Not in substance use treatment
 - Own a smartphone
- Complete baseline assessment (~40 minutes)
- Randomization stratified by gender and severity of use
- Two groups:
 - Smart Phone App Brief Intervention (SP-BI) (12 weeks)
 - Enhanced Usual Care (EUC) (Brochure with Resources)
- 4, 8, 12 month follow-up assessments
- Payment: \$35 each/four assessments

Study Progress

IRB:

- All sites (Case, UM and UT) have both IRB and HRPO approval
- Certificate of Confidentiality obtained from NIH

Project Development:

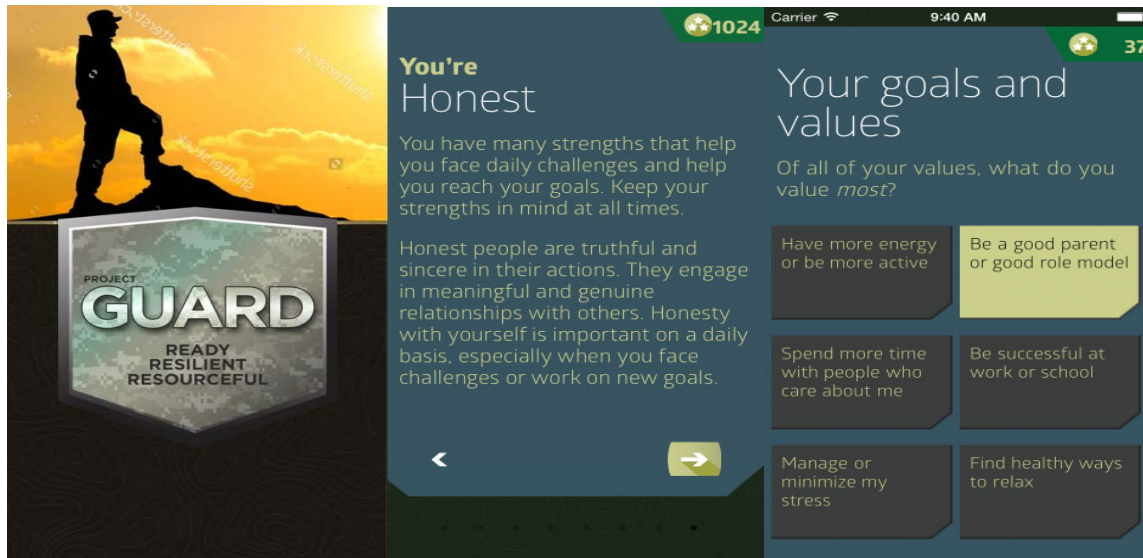
- Twice monthly meetings to work on IRB materials, Certificate of Confidentiality, ClinicalTrials.gov, and coordination with all IRB's
- Monthly meetings between Case, Michigan and Toledo to develop protocols, surveys, app intervention, manuals, etc.
- Weekly meetings with app developers to design app, provide feedback, test and tweak
- Regular meetings with Ohio Guard Advisory Board-providing insight and feedback during the app development stage

Recruitment:

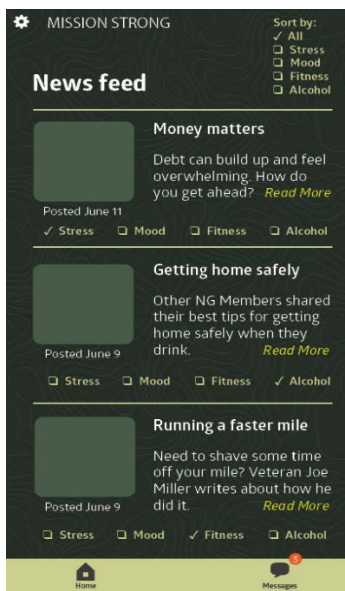
- First set of alert letters went out March 7, 2017

Screenshots of Smartphone App

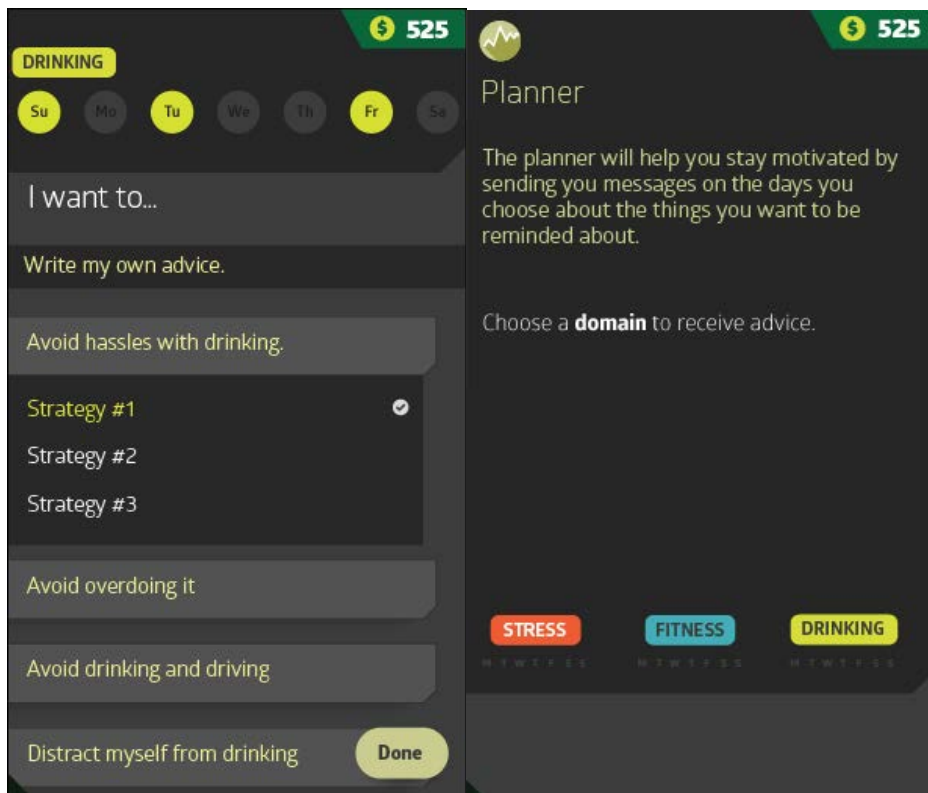
Brief Intervention



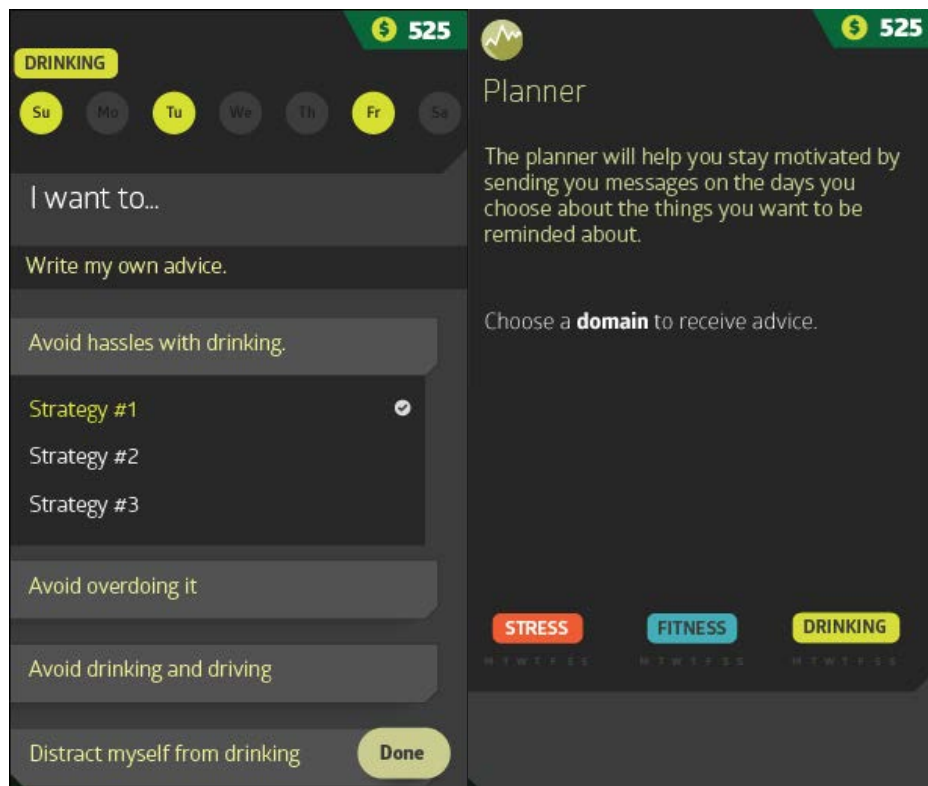
Newsfeed



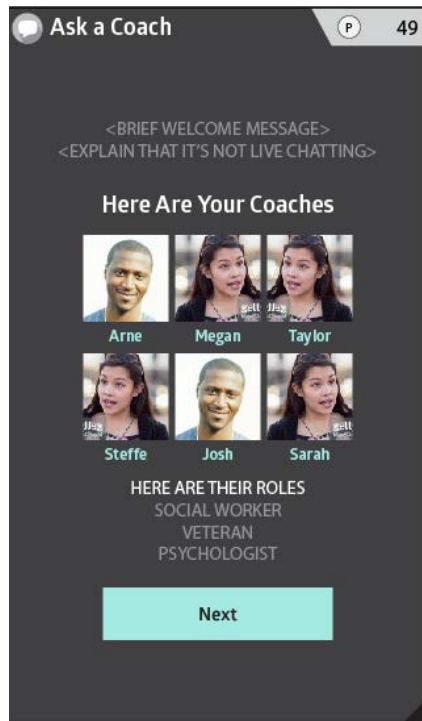
Weekly Planner



Daily Tracker



Ask the Health Coach



Follow On Work

- eHealth app interventions have many advantages, including the ability to present detailed interactive interventions and allow the Guard member to establish personalized plans for change and receive frequent reminders, updated information and virtual support services.
- Based on results of these two studies (this phone app intervention and the NIAAA Web-based intervention) additional innovations will be proposed and tested in National Guard and other Reserve components.
- Results from this study will inform future studies that attempt to further refine and increase the impact of population eHealth interventions on key substance use and other mental health problems in reserve component members.

Feedback from the AAB attendees was positive. There was some discussion about the possibility of the app replacing the current annual training already done by the Guard should the results of the study be positive. The ONG is interested in learning if binge episode drinking is higher during drill weekends and if it is part of the culture. This is something the study team may look at when analyzing the data at the end of the study.

Task #5: Regulatory & Reporting – 42% completed

University Hospitals Institutional Review Board (IRB)

- The University Hospitals Institutional Review Board (IRB) - The most recent continuing review was approved on January 24, 2017. The current expiration date for the study is January 23, 2018.

- USAMRMC ORP HRPO –UHCMC sent its original HRPO application on April 15, 2016. Initial HRPO approval was received on January 31, 2017.

University of Toledo (UT)

- The University of Toledo Biomedical Institutional Review Board - The original IRB submission was approved on September 15, 2016. The current expiration date for the study is March 6, 2018.
- USAMRMC ORP HRPO –UT sent its original HRPO application on September 26, 2016. Initial HRPO approval was received on January 31, 2017.
- The site PI at University of Toledo was changed from Dr. Marijo Tamburrino to Dr. John Wryobeck, as Dr. Tamburrino retired effective May 31, 2017. The UT IRB approved this change on May 18, 2017. This change was sent to USAMRMC HRPO on May 23, 2017 and was approved June 5, 2017.

University of Michigan (UM)

- University of Michigan Medical School Institutional Review Board (IRBMED) - The original IRB submission was approved on September 24, 2016. The current expiration date for the study is September 23, 2017.
- USAMRMC ORP HRPO – UM sent its original HRPO application on August 29, 2016. Initial HRPO approval was received on February 26, 2017.

Based on a call with Dr. Carly Kiselycznyk, Dr. Ray Santullo, Dr. Katharine Nassauer and study staff from UHCMC and UM on December 1, 2016, it was decided that monetary incentives (contingency management) would be removed from the app while keeping other virtual gamification elements in the app. This change was submitted to and approved by all IRBs in the 1st quarter of 2017. Documents related to this change were submitted to HRPO for all sites and were included in the review of the original applications.

Since the study began enrollment, the Data Safety Monitoring Board has met twice. As there have been no AEs or SAEs since the study began, they had no concerns with the study continuing as is.

What opportunities for training and professional development has the project provided?

This project has provided Ann Mary Mercier, MPH, Study Coordinator at University of Toledo, with the opportunity to work on a large-scale, multi-site, USAMRAA funded study. She has gained additional skills and knowledge related to the recruitment and retention of human subjects including the informed consent process, the use of REDCap, interacting with study participants and the suicidality triage process. She has also had the opportunity to work with collaborating sites to provide feedback on the creation of the study database and procedural manuals.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Task #1: Customize Computer Intervention for National Guard (NG) population

CHCR will continue to provide ongoing support for the app throughout the enrollment period.

Task #2: Data Collection

Over the next year, study staff will continue to pre-screen and enroll subjects who are eligible based on their platform project telephone surveys. We also plan to begin recruiting outside of the platform project in order to achieve our enrollment goal. We have submitted an updated Statement of Work and letter explaining the change to our institution business official, who will then submit these documents to our grants officer for review and approval. Once approval for our proposed plan described above is obtained from ONG leadership, we will amend the protocol at all sites and obtain IRB approval for the new recruitment procedures and then submit to HRPO for approval. We hope to be to start recruitment outside of the platform project in late 2017/early 2018.

Task #3: Data Dissemination

Nothing to Report

Task #4: Oversight Meetings

Study staff will attend the 2017 Substance Abuse IPR being held September 27-28, 2016. The next meeting of the Scientific Advisory Board meeting was planned for fall 2017 but due to the schedules of the PIs and the delay in being able to recruit new subjects in to the main platform project, this will be postponed to late 2nd quarter 2018. The Data Safety Monitoring Board will continue to meet quarterly.

Task #5: Regulatory & Reporting

Over the next reporting period, we will continue to submit quarterly financial and technical reports to USAMRAA as required. In addition, we wait to hear from the USAMRMC Office of Research Protections Human Research Protection Office regarding approval to begin enrollment.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Removing contingency management from the app at the request of USAMRAA lead to a delay in starting recruitment. In addition, we are finding that more participants in the platform project are no longer in the OHARNG than originally anticipated, thus making them ineligible for the study. We plan to begin recruiting outside of the platform project by attending Personal Health Assessment weekends for the OHARNG and having a table set up to provide information to soldiers on the project and the opportunity to be pre-screened/enrolled if they are eligible and interested. Finally, recruitment of new subjects in to the platform project for this wave has been delayed as we await the yearly letter from the aTAG that is included in the alert letter packet. However, we anticipate recruitment of new subjects to be in October of 2017.

Changes that had a significant impact on expenditures

Delaying the startup of the study impacted expenditures, as has low recruitment.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

No activities involving the use or care of vertebrate animals will be performed to complete this project.

Significant changes in use of biohazards and/or select agents

No activities involving the use biohazards and/or select agents will be performed to complete this project.

- 6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Nothing to Report

- **Books or other non-periodical, one-time publications.**

Nothing to Report

- **Other publications, conference papers, and presentations.**
Nothing to report.
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Technologies or techniques**
Project GUARD app
- **Inventions, patent applications, and/or licenses**
Licenses to place Project GUARD app on iPhone and Android app stores
- **Other Products**
Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Joseph R. Calabrese, MD

Project Role: Principal Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - jcalabrese

Nearest person month worked: 0.3 calendar months

Contribution to Project: Oversight and ongoing administration of all aspects of the Ohio Army National Guard Mental Health Initiative. Dr. Calabrese provides oversight of the sites and serves as the liaison between the Scientific PI and the Steering Committee of the primary platform project. Dr. Calabrese is also the primary liaison with the Ohio Army National Guard leadership.

Name: Mary Beth Serrano, MA

Project Role: Project Manager

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1.8 calendar months

Contribution to Project: Ms. Serrano provided administrative support during this reporting period and ongoing grant and fiscal management including payment of subcontracts, employee reimbursement, and sub-contract execution and monitoring.

Name: Brittany Brownrigg, BS

Project Role: Data Coordinator

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1.05 calendar months

Contribution to Project: Ms. Brownrigg provided ongoing data management support and worked with the sites to quality assure data in real time. She provides ongoing maintenance to the database as needed.

Name: Nicole Moomaw, BA

Project Role: Research Coordinator II

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 7.8 calendar months

Contribution to Project: Ms. Moomaw has been responsible for the recruitment and enrollment of participants. She has worked with participants to expedite the completion of the consent process and baseline intervention. She follows up with participants as needed and continues to work on the content for the application and responding to participant questions and concerns.

Name: Carla Conroy

Project Role: Research Coordinator II

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1.20 calendar months

Contribution to Project: Ms. Conroy has been responsible for the management of the IRB protocol and oversight of approvals from the respective IRBs and HRPO as well as maintaining regulatory documents across the sites. In addition, she has coordinated with the sites and provided feedback regarding ongoing enrollment and recruitment.

Name: John Wryobeck, PhD

Project Role: Co-investigator

Researcher Identifier (e.g. ORCID ID): n/a

Nearest Person Month: 3 calendar months annually

Contribution to Project: Dr. Wryobeck has been involved in creating and testing the mobile-based app intervention as well as survey. He is supervising the work of the University of Toledo-based research assistant and is involved in ongoing discussions and planning for increasing participant recruitment.

Name: Ann Mary Mercier

Project Role: Research Assistant

Researcher Identifier (e.g. ORCID ID): n/a

Nearest Person Month: 12 calendar months annually

Contribution to Project: Ms. Mercier continues to utilize RedCap through University Hospitals (UH) in Cleveland for participant recruitment and assessment. She is now handling IRB amendments and renewals at the University of Toledo for this project. Ms. Mercier also participated in an additional Suicide Risk Assessment training at University Hospitals (UH) in Cleveland. Ms. Mercier has contributed the following: 1) created app content for the brief intervention (newsfeeds for 12 weeks, Health Coach introductions and tips planner messages, media library images and infographics), 2) researched HIPAA-compliant alternatives for remote communication with participants, 3) developed an app cheat sheet for FAQs, 4) created an app issues tracking sheet, 5) maintained a list of app and newsfeed-related issues and monitored issue progress, 6) created an app “how-to” manual, 7) created a project EndNote account with content references, 8) maintained all aspects of the app newsfeed (blog postings, confederate comments, replies to participant comments), 9) co-monitored the app health coach function, 10) conducted multiple pre-screening/consenting practice sessions with UH research assistant, 11) conducted multiple pre-screening/consenting and follow-up sessions with participants, and 12) updated literature regarding MHealth app utilization in behavioral health and substance use prevention. In

addition, Ms. Mercier has participated in bi-weekly inter-institutional project teleconferences and bi-weekly research assistant teleconferences with her colleague at University Hospitals (UH), two PI meetings, and weekly supervisory meetings.

Name: Frederic C. Blow, PhD

Project Role: Scientific Principal Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - fredblow

Nearest person month worked: 3.0 calendar months

Contribution to Project: Dr. Blow has provided ongoing oversight of the initiative.

Name: Kristen Barry Haenchen, PhD

Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - kbarry

Nearest person month worked: 1.6 calendar months

Contribution to Project: Dr. Haenchen provided input for the develop intervention content for the mobile phone app and input with the recruitment phase of the study.

Name: Lynn Massey, LMSW

Project Role: Project Manager

Research Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 2.3 calendar months

Contribution to Project: Ms. Massey coordinated with CHCR to finalize and beta test the app and has been a liaison when issues arose in the app since recruitment began. She has provided guidance around recruitment issues and has co-led monthly Investigator meetings.

Name: Rose Ignacio

Project Role: Data Manager/Analyst

Research Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 2.0 calendar months

Contribution to Project: Ms. Ignacio worked on developing data dictionaries and data analytic plans during this reporting period.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

Not applicable

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

Quad Chart attached

9. APPENDICES

Study Enrollment Flowcharts

Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

Log Number: 13277015

Award Number: W81XWH-14-2-0007



PI: Joseph R. Calabrese, M.D

Org: Case Western Reserve University

Award Amount: \$3,667,349

Study Aims

Specific Aims

1. Compare the MT-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 4, 8, and 12 months post-intervention.
2. Compare the MT-BI and EUC conditions for binge drinking at 4-, 8- and 12 months

Secondary Aims

1. Compare the MT-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 4-, 8- and 12 months.
2. Examine the impact of the interaction of deployment status with intervention condition (MT-BI or EUC) on 4-, 8- and 12-month measures of alcohol and drug use

Approach

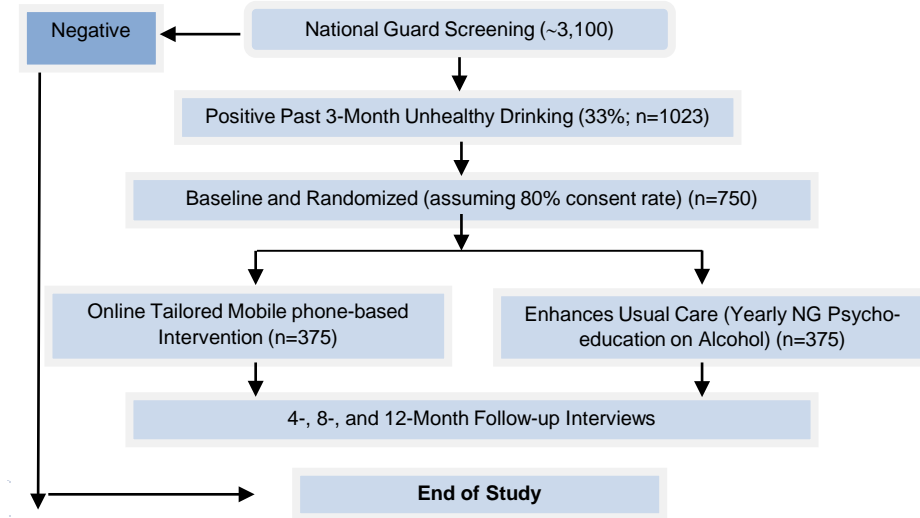
- The proposed project is a fully-powered randomized controlled trial of a smartphone app-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 4 months.
- After tailoring the content of the MT- BI intervention for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the OHARNG MHI, to identify 750 participants with unhealthy drinking.
- These Guard members will then be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

Timeline and Cost

Activities	CY	14-15	15-16	16-17	17-18	18-19
Customize Intervention/ App for National Guard (NG) population						
Data Collection						
Data Dissemination						
Oversight Meetings						
Estimated Budget		\$1.1mil	\$623K	\$631K	\$644K	\$652K

Updated: 09/12/2017

Study Design Overview



Goals/Milestones

CY14-15 Goals: ☒ Customize Intervention/App ☒ Data Collection

☒ Oversight Meetings

CY15-16 Goals: ☒ Customize Intervention/App ☒ Data Collection

☒ Oversight Meetings

CY16-17 Goals: ☒ Data Collection ☒ Oversight Meetings

CY17-18 Goals: ☐ Data Collection ☐ Data Dissemination

☐ Oversight Meetings

CY18-19 Goals: ☐ Data Dissemination ☐ Oversight Meetings

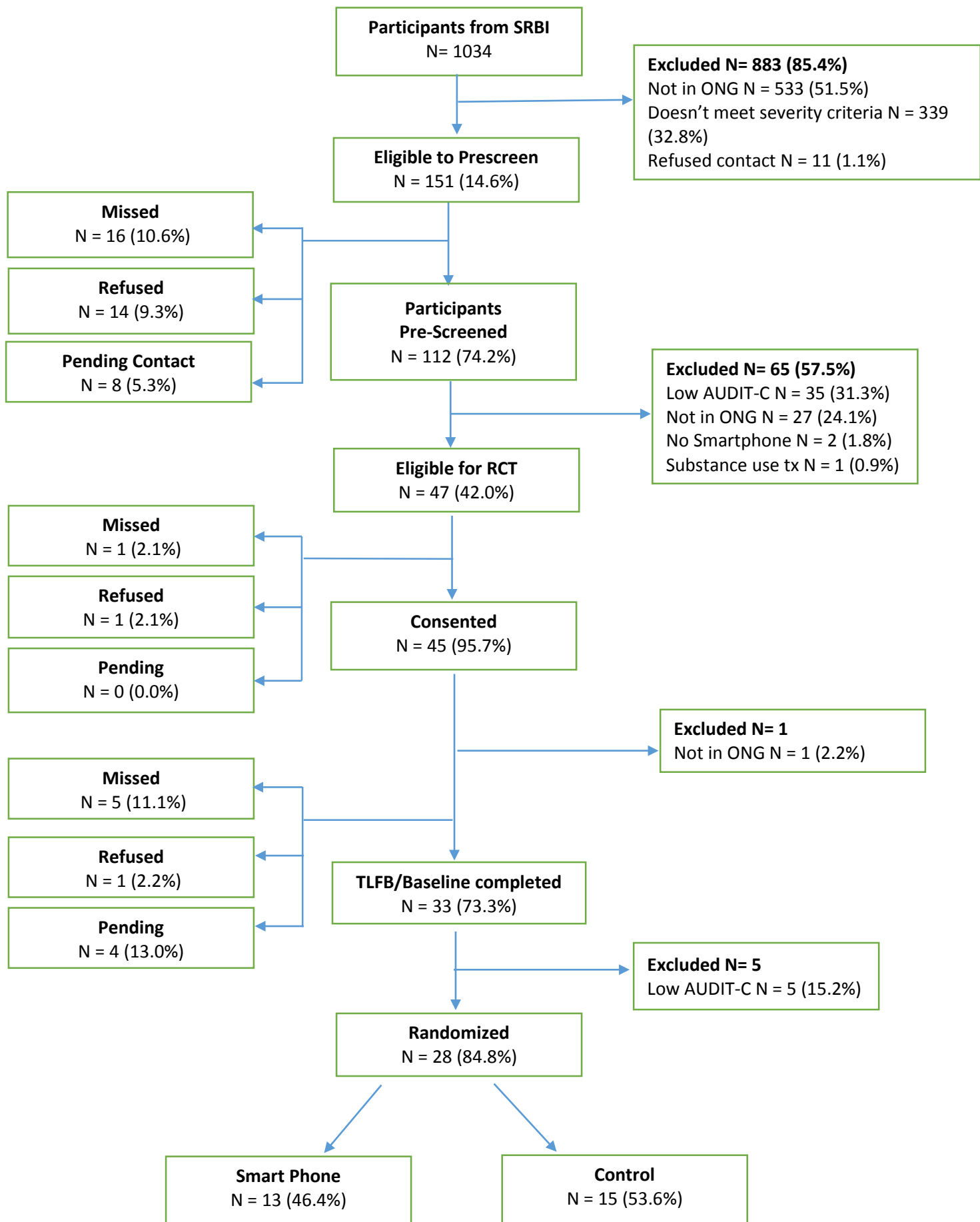
Comments/Challenges/Issues/Concerns

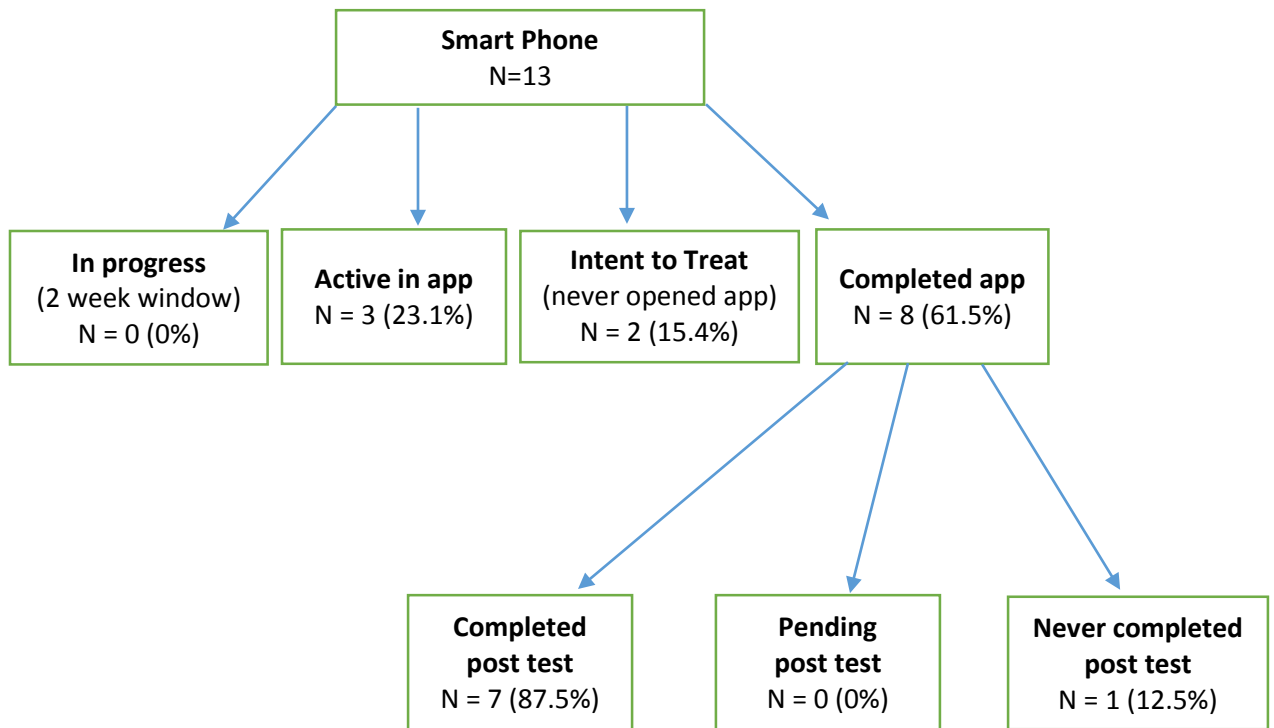
Enrollment has been slower than expected as a large number of subjects in the primary platform study are no longer active in the OHARNG (54.2%), which is an inclusion criteria for participation in the study. Recruitment of new subjects in the platform project is expected to begin in late Fall 2017. These soldiers will be those who have enlisted in the OHARNG since January 2016. We anticipate that most of these soldiers will still be active in the OHARNG, which will help with recruitment. We are also planning to recruit outside of the OHARNG study as well to assist with meeting our recruitment goal.

Budget Expenditure to Date

Projected Expenditure: \$2,370,780

Actual Expenditure: \$1,582,331





4 Month Follow Up

Smart Phone N = 7	Control N = 9	Total N = 16
In Progress (≤ 14 days) N = 0 (0.0%)	In Progress (≤ 14 days) N = 1 (11.1%)	In Progress (≤ 14 days) N = 1 (6.3%)
Outstanding (>15 days) N = 4 (57.1%)	Outstanding (>15 days) N = 1 (11.1%)	Outstanding (>15 days) N = 5 (31.3%)
Completed N = 3 (42.9%)	Completed N = 7 (77.8%)	Completed N = 10 (62.5%)
Not Completed N = 0	Not Completed N = 0	Not Completed N = 0